

Remarks

Applicants have amended claims 22, 31, and 40-41, and added a statement regarding the priority/benefit applications as requested by the Examiner. The amendments find support throughout the specification and claims as originally filed, and thus no new matter has been added.

Claims 22-41 are pending.

I. Objection to the Specification

The Examiner has objected to the specification, alleging that "the instant specification does not contain the required [priority] statement at the beginning of the specification."

In response, Applicants do not agree that such a statement is required to be added to a national stage application when priority was properly claimed in the international application. However, in an effort to expedite prosecution, the specification has been amended to include the statement as requested by the Examiner, thus obviating the objection. Applicants point out that pursuant to 37 C.F.R. § 1.78(a)(2)(ii)(C), the time period of 37 C.F.R. § 1.78(a)(2)(ii) does not apply to the instant application, and thus the instant statement is timely. Accordingly, Applicants respectfully request that the statement be entered and the instant objection be reconsidered and withdrawn.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 22-41 as allegedly indefinite, arguing that "it is unclear what is the 'representation'." The Examiner suggested that the "represented by" language be removed so that reference is only made to certain nucleotides of SEQ ID NO:51.

In response, while Applicants disagree and maintain that the previously pending claims were clear and definite, Applicants have removed the "represented by" language in independent claims 22 and 31 as suggested by the Examiner, thereby obviating the rejection. Accordingly, Applicants respectfully request that the instant rejection be reconsidered and withdrawn.

III. Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 40-41 as allegedly not enabled. In particular, the Examiner asserts that the specification "does not reasonably provide enablement for methods of detecting *B. burgdorferi* in a biological sample."

In response, while Applicants respectfully disagree and maintain that the previously pending claims were fully enabled, Applicants have added the phrase "by nucleic acid hybridization or PCR" to claims 40-41. Thus, the claims specify both the type of assay and the principal reagent to be used. The specification clearly enables the use of the polynucleotides recited in claims 40-41 for detection of *B. burgdorferi* in a biological sample using hybridization or PCR-based assays. In particular, the specification at page 35, line 15 to page 38, line 2 teaches how to use such polynucleotides in diagnostic assays and kits. "Analysis of nucleic acid specific to *Borrelia* is assayed by PCR or hybridization techniques using nucleic acid sequences of the present invention as either hybridization probes or primers." Specification at page 35, lines 19-21; *see also* page 27, lines 5-28; page 8, line 31 to page 9, line 2; page 14, lines 16-21; page 17, line 35 to page 18, line 2; and page 18, lines 18-26. Pages 35-38 of the specification teaches a variety of well known techniques for such assays, including Northern blot analysis, S1 nuclease mapping, PCR, RT-PCR, RFLP analysis, and bio chip technology.

Thus, one skilled in the art could easily practice the claimed methods without undue experimentation, especially in light of the high level of skill in the art, the predictability of nucleic acid hybridization and PCR, and the guidance provided by the specification. Accordingly, Applicants respectfully request that the instant rejection be reconsidered and withdrawn.

Conclusion

Entry of the above amendment is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: November 10, 2004

Respectfully submitted,

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Application No.: 09/830,228

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Docket No.: PB370US

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

1. Fax Cover Sheet
2. Fee Transmittal Sheet
3. Response And Amendment Under 37 C.F.R. § 1.111

I hereby certify that the above-listed correspondence is being facsimile transmitted to the United States Patent and Trademark Office on November 10, 2004.

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